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			*	ROYDS, LESLIE A	
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				1614	
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	SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/085,239	WARD ET AL.			
Office Action Summary	Examiner	Art Unit			
	Leslie A. Royds	1614			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
 1) ⊠ Responsive to communication(s) filed on 29 Ja 2a) ☐ This action is FINAL. 2b) ☒ This 3) ☐ Since this application is in condition for allowant 	This action is FINAL . 2b)⊠ This action is non-final.				
Disposition of Claims					
4) Claim(s) 40-47 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 40-42 and 44-47 is/are rejected. 7) Claim(s) 43 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

DETAILED ACTION

Claims 40-47 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed January 29, 2007 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 40-47 are pending and under examination. Claims 40-42 are amended and claims 44-47 are newly added.

Applicant's arguments, filed January 29, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Claims

Claim 43 remains objected to for depending upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 40 is directed to a method for treating a hyperproliferative disease of the skin subject to treatment by inhibition of the retinoic acid biosynthetic pathway, wherein said disease is, e.g., a disorder of keratinization, consisting essentially of administering, to a patient in need thereof, an inhibitor of the retinoic acid biosynthetic pathway, wherein said inhibitor is carbenoxolone. Present claim 44 is also directed to a method for treating a hyperproliferative disease of the skin subject to treatment by inhibition of the retinoic acid biosynthetic pathway, where said disease is, e.g., a disorder of keratinization, comprising topically administering to skin of a patient in need thereof, an inhibitor of the retinoic acid biosynthetic pathway, wherein said inhibitor is carbenoxolone.

In particular, the specification fails to provide adequate written description for the genus of disorders of keratinization.

MPEP §2163 states, "The issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not convention in the art or known to one of ordinary skill in the art...The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555,

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1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))... Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant states at page 51, lines 15-20 of the specification, "Skin hyperproliferation diseases which may be treated by using the methods and compositions of our invention include psoriasis, acne vulgaris, acne rosacea, actinic keratosis (solar keratosis-squamous carcinoma *in situ*), the ichthyoses, hyperkeratoses, disorders of keratinization such as Darriers disease, palmoplantar keratoderma, pityriasis rubra pilaris, epidermal naevoid syndromes, erythrokeratoderma variabilis, epidermolytic hyperkeratoses, non-bullous ichthyosiform erythroderma, cutaneous lupus erythematosus and lichen planus."

First, it is noted that this citation from the instant specification does not clearly delineate whether Applicant has provided Darriers disease as the sole exemplary disorder of keratinization or whether Applicant has provided Darriers disease, palmoplantar keratoderma, etc. as exemplary disorders of keratinization. The presence of the comma between the "hyperkeratoses" and "disorders of keratinization" and the lack of a conjunction (such as "and" between such terms) is supportive of the interpretation that Applicant has solely provided Darriers disease as an exemplary disorder of keratinization.

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While such an exemplary disorder is duly noted, it remains that Applicant has failed to provide any limiting definition of the genus of "disorders of keratinization" that Applicant was in possession of, and intended to be treated using the presently claimed inhibitor of the retinoic acid biosynthetic pathway (i.e., carbenoxolone), at the time of the invention. In other words, Applicant has failed to define this genus of disorders in such a manner as to provide adequate written description of the full scope of the claimed genus.

Keratin dysfunction is known in the art to occur via mutations in genes encoding keratin intermediate filaments. Accordingly, given that there are various keratin genes in which the mutations can occur, and further given that mutations in different genes will clearly result in a disorder distinct from another disorder resulting from a mutation in a completely different keratin gene, the genotypes and phenotypes of disorders associated with keratin vary significantly such that the exemplification of a single disorder, i.e., Darriers disease, is not a reasonably representative set of species. It has been held in patent law that when there is substantial variation within a genus, Applicant is required to describe a sufficient variety of species to reflect the variation within the genus.

Though Applicant's claims do not circumscribe the treatment of any disease, but rather are limited to those disorders that are associated with keratinization, it is noted that Applicant has failed to provide guidance as to how one of ordinary skill in the art would go about identifying those disorders that were associated with keratinization (i.e., keratin dysfunctions) and, thus, would have been amenable to treatment with the presently claimed compound carbenoxolone, aside from the single disorder expressly disclosed, without having to execute hit or miss testing practices in a variety of different disorders to determine if such disorders were caused by keratin dysfunction and were amenable to the claimed carbenoxolone therapy.

The fact that the instant specification fails to clearly delineate the metes and bounds of the claimed genus of disorders of hyperkeratinization and, further, fails to provide a reasonably representative

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set of species of keratin disorders to show that Applicant was actually in possession of the full scope of the claimed genus, is clearly indicative that the instant specification lacks adequate written description for the claimed genus of disorders of keratinization. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that

the Applicant was in possession of the claimed invention." Please reference MPEP §2163.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of administering the presently claimed compound for the treatment of any disorder of keratinization.

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

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Present claims 44-47 are directed to a method of treating a hyperproliferative disease of the skin subject to treatment by inhibition of the retinoic acid biosynthetic pathway, said disease selected from the e.g., psoriasis, acne vulgaris, actinic keratosis, solar keratosis, squamous carcinoma *in situ*, ichthyoses, hyperkeratosis and disorders of keratinization, comprising topically administering to skin of a patient in need thereof an inhibitor of the retinoic acid biosynthetic pathway, wherein said inhibitor is carbenoxolone.

In particular, the claim fails to clearly delineate whether the skin of the patient in need thereof is skin that is affected by the claimed hyperproliferative disease (e.g., psoriasis, acne vulgaris, actinic keratosis, solar keratosis, squamous carcinoma *in situ*, ichthyoses, hyperkeratosis, disorder of keratinization) or if it is *any* skin on the subject in need of treatment of any one or more of the claimed hyperproliferative diseases. In other words, it is unclear whether Applicant intends to topically apply the claimed compound carbenoxolone to diseased skin of the subject being treated or if Applicant intends to topically apply the claimed compound to any area of skin of the subject being treated.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

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Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-42 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchardt et al. (WO 97/15298; 1997), already of record, for the reasons of record set fort at pages 2-3 of the previous Office Action dated July 27, 2006, of which said reasons are herein incorporated by reference.

Burchardt et al. teaches the treatment of acute and chronic inflammatory disorders, such as psoriasis (page 6, lines 1-11), using a glucocorticosteroid, such as carbenoxolone sodium and an LTD4 receptor antagonist (page 1, lines 4-6 and page 2, lines 3-7). Burchardt et al. expressly discloses that the combination can be used topically as an ointment or cream for application to the skin (page 6, lines 18-20).

Newly amended claims 40-42 remain properly included in the present rejection. Regarding the use of the transitional phrase "consisting essentially of", the MPEP states at §2111.03[R-3], "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention...For the purposes of searching for and applying prior art under 35 U.S.C. §102 and §103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising'."

Applicant has failed to definitively point out the basic and novel characteristics of the invention. Accordingly, in view of the guidance provided in the MPEP at §2111.03[R-3], Applicant's newly amended claim language, i.e., from "comprising" to "consisting essentially of", will properly be interpreted as being equivalent to "comprising" for the purposes of searching and applying prior art under

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the 102 and/or 103 statute(s) in the absence of any clear indication in the specification or claims of the basic and novel characteristics of the invention.

Newly added claims 44-46 are properly included in the present rejection because Burchardt et al. clearly and unequivocally teaches topical application of the disclosed therapeutic combination. Further, it is again noted that the present claims contain the transitional phrase "comprising", which is open transitional language and does not patentably exclude the presence or administration of additional components, such as the LTD4 receptor antagonist of Burchardt et al., to the presently claimed subject. Please see MPEP §2111.03[R-3] for discussion of the interpretation of claim transitional language.

Response to Applicant's Arguments

Applicant traverses the application of Burchardt et al. as prior art against the claimed invention, stating that the claims as previously presented clearly indicated that the claimed method comprised the administration of only a single inhibitor of retinoic acid. Applicant relies upon the specification at pages 100-101 (Table 6 of the Proliferation Assay), which clearly shows "that carbenoxolone was administered in the presence of no other inhibitors (see line 6 of Table 6)." Applicant further relies upon the results shown in Figure 10, which shows that carbenoxolone provided the greatest reduction in proliferation. Applicant further submits that the claims are clearly allowable over Burchardt et al. because they indicate that only a single inhibitor of retinoic acid is administered, as opposed to the LTD4 receptor antagonist-glucocorticosteroid combination of Burchardt et al. Applicant additionally asserts that Burchardt et al. fails to disclose carbenoxolone sodium as a particularly preferred glucocorticosteroid and that psoriasis is only disclosed as one of a long list of "suitable indications".

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

First, Applicant's assertion that the claimed method comprises the administration of only a single inhibitor of retinoic acid is not disputed insofar as it is recognized that Applicant's claims are directed to

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the administration of "an inhibitor of the retinoic acid biosynthetic pathway". However, though the claims recite the administration of carbenoxolone as said inhibitor of the retinoic acid biosynthetic pathway, it remains that the claimed method does not preclude the presence of additional components and/or steps. This is true for the claims that are directed to "consisting essentially of" (claims 40-42) because, as noted above, the transitional phrase "consisting essentially of" is construed as "comprising" absent a clear indication by Applicant of what the basic and novel characteristics of the invention. It is also true for the claims that are directed to "comprising" (claims 44-46), because such language is clearly open and does not patentably exclude additional method steps or administration of additional components.

Applicant is reminded that it is the transitional phrase that follows the preamble language that controls the closed or open nature of the claim as a whole. Accordingly, the fact that Applicant recites "consisting essentially of" or "comprising" following the preamble objective of treating a hyperproliferative disease of the skin subject to treatment by inhibition of the retinoic acid biosynthesis pathway, wherein said disease is psoriasis, acne vulgaris, etc., is clearly and obviously indicative of the fact that the claim, as a whole, is still open to the inclusion of additional elements, such as the LTD4 receptor antagonist of Burchardt et al. The fact that the claim(s) state "wherein the inhibitor is carbenoxolone" does not limit the elements or steps of the claimed method solely to the administration of carbenoxolone. The placement of the transitional language and the presence of the word "is" only requires that, in order to meet the claim limitations, that carbenoxolone is administered to a subject suffering from any one or more of the claimed diseases. This claimed requirement is clearly and unequivocally met by the teachings of Burchardt et al.

Applicant's reliance upon Table 6 and Figure 10 in support of the allegation that the specification clearly *intends* for carbenoxolone to be administered as a single agent is not at all persuasive because the claims fail to reflect this intent to solely administer a single agent (i.e., carbenoxolone). The claims recite

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open transitional language and do not preclude the administration of additional active agents. Moreover, Applicant is reminded that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In other words, and as stated at MPEP §2111.01(II), "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004)."

It is insufficient for Applicant to rely upon an embodiment presented in the specification as being clearly representative of the *intent* to administer a single agent (i.e., carbenoxolone), particularly in view of the fact that the claims are clearly not limited in such a manner. Applicant is reminded that, even though the specification discloses an embodiment wherein carbenoxolone is administered as the sole agent, *it is the claims that must be able to stand alone in defining the invention fully, clearly and precisely.* Accordingly, if Applicant desires to preclude the administration of any additional agent, especially the LTD4 receptor antagonist of Burchardt et al., then the claims must be amended in such a manner as to clearly close the claim(s) to the administration of a single, sole active agent (carbenoxolone).

Regarding Applicant's arguments that carbenoxolone sodium is not a particularly preferred glucocorticosteroid and psoriasis is only one of a long list of possible uses for the disclosed therapeutic combination of Burchardt et al., it appears that Applicant is once again restricting his consideration of the reference solely to that which is preferred and disregards the broader teachings of the reference as a whole. First, Applicant is again reminded that the disclosure of a reference is not limited only to that which is preferred or even solely to that which is claimed or exemplified. Applicant is directed to the MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed

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examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." (emphasis added) Thus, Applicant's traversal based upon the fact that carbenoxolone sodium is not a particularly preferred glucocorticosteroid is clearly not persuasive because Applicant is not entitled to ignore the broader disclosure of the reference in order to assert patentable distinction over the prior art. Please see Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

Furthermore, the fact that psoriasis is one disorder out of various other disorders that are disclosed does not negate the fact that such a disorder is clearly and unequivocally named in the disclosure of Burchardt et al. as being amenable to disclosed glucocorticosteroid-LTD4 receptor antagonist therapy. As previously stated in the prior Office Action at pages 5-6, the broader teachings of the reference are not negated on the basis of the comprehensiveness of the teachings. Please reference the MPEP at §2131.02 (see "A Reference That Clearly Names the Claimed Species Anticipates the Claim No Matter How Many Other Species Are Named"), which states, "A genus does not always anticipate a claim to a specie within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ 2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. §102(a), in that publication."). Id. at 1718. See also In re Sivaramakrishnan, 673 F.2d 1383, 213 USPO 441 (CCPA 1982)."

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For these reasons provided supra, and those previously made of record at pages 2-7 of the

previous Office Action dated July 27, 2006, rejection of claims 40-42 and 44-46 is proper and is

maintained.

Conclusion

Rejection of claims 40-42 and 44-47 is proper and is maintained.

Claim 43 remains objected to for depending upon a rejected base claim.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should

be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally

be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin

H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this

application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application

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Patent Examiner

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